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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,609	03/30/2004	Paul Re	H-US-01403CON	3229
50855 7590 12/17/2010 Tyco Healthcare Group LP d/b/a Covidien 555 Long Wharf Drive Mail Stop 8-N1, Legal Department New Haven, CT 06511				
EXAMINER				
BACHMAN, LINDSEY MICHELLE				
ART UNIT		PAPER NUMBER		
3734				
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12/17/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,609

Applicant(s)

RE ET AL.

Examiner

LINDSEY BACHMAN

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 9, 16, 17 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 9, 16, 17 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 7 December 2010.

Response to Arguments

Applicant's arguments filed 7 December 2010 have been fully considered but they are not persuasive.

Regarding Claim 1, Applicant argues that the frame 10 of Bray'034 is not integrally formed with the cover portion. This limitation is treated as a product by product limitation. Product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113. The final, deployed product of Bray'034 contains a cover that is integral with the frame.

Further regarding Claim 1, Applicant argues that the screw of Bray'034 needs to contain a head in order to hold the plate on the bone and that the screw of Small'499 preferably does not contain a head, so substituting an axial bore in Small'499 in for the screw head of Bray'034 would not function as needed for Bray'034. However, the rejection does not suggest removing the head from the screw of Bray'034 - it merely suggests using an axial bore for engagement with a deployment member rather than the typical screw head (e.g. Phillips or flathead contours). Further, Small'499 explicitly states at column 3, lines 20-27 that the screw may contain a head, if needed.

Regarding Applicant's assertion that modifying the screw of Bray'034 to contain a channel as taught by Small would compromise the integrity of the screw and its engagement with the base plate, Applicant has not provided any reasons for this assertion.

Regarding Claim 20, Applicant argues that Bray'034 does not disclose a method of receiving a distal end of an insertion tool within the central channels of each of the leg members and driving each leg of the leg structure of the encapsulation device into the hole provided therefore in the bone to bring a distal surface of the bowed encapsulation device body into adjacency with the body." Although this step is performed to each screw individually in the method of Bray'034 in view of Small'499, tightening/driving the screws into bone brings the bowed encapsulation device into closer contact with the bone compared with before the encapsulation device is attached to bone.

Claim Objections

Examiner would like to note that the amendment to Claim 1 was not properly identified with strikethroughs, underlines, etc. Claim 1 added the term "integrally formed" on line 11, not just the word "formed" as indicated by Applicant.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 3, 9, 20-24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bray (US Patent 6,235,034) in view of Small et al. (US Patent 5,139,499).

Claim 1, 3, 9: Bray'034 discloses device having a body that has a generally annular frame (14; shown in Figure 5 and 6a and shape described at column 4, lines 40-42) supporting a solid shell-like cover (20). The device contains elongated leg structures (16) extending from the distal side of the body for placement in the bone. The legs (16) are thicker than the body and have a portion at the distal end of the legs that are enlarged beyond a periphery of the leg member (screw threading). The frame has a peripheral frame portion (33). The cover is integral with the frame (Figure 5) and bowed proximally (column 4, lines 48-50 and column 5, lines 29-31). The final, deployed product of Bray'034 contains a cover that is integral with the frame. The limitation "...said cover portion being integrally formed with said frame portion..." is being treated as a product-by-product limitation. Product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Bray'034 doesn't teach that the leg structures are generally conical or that the leg structures have a central channel that extends substantially the length of each leg.

Small'499 teaches providing a bone screw with a central channel (26) in order to engage with a delivery device (Figure 3). Small'499 also teaches that it is known to make the bone screw generally conical. It would have been obvious to one of ordinary

skill in the art to modify the leg members of Bray'034 with the teachings of Small'499 (conical structure and central channel) so that it has the above stated advantages.

Claim 20: Bray'034 teaches a method of repairing an articular cartilage defect (column 2, lines 47-50 and column 1, lines 46-58) using a device that contains a body (Figure 5, 6a) with elongated legs (16). The device contains a body having a circular frame portion (14; column 4, lines 40-42) and a solid, shell-like cover (20) fixed within the frame. The cover is bowed proximally (column 4, lines 48-50 and column 5, lines 29-31). Bray'034 teaches creating a hole in the bone for each leg and then placing the legs into the hole to place the bowed encapsulation body adjacent to the bone (column 6, lines 57-63). Bray'034 does not teach that the legs have a channel extending substantially the length of the legs.

Small'499 teaches providing a bone screw with a central channel (26) in order to engage with a delivery device (Figure 3). It would have been obvious to one of ordinary skill in the art to modify the leg structures in the method of Bray'034 with the teachings of Small'499 so that it too has this advantage.

Claim 21, 22: Bray'034 in view of Small'499 teach a channel, but do not teach a channel that is tapered. Small'499 teaches that the channel is shaped to engage with a deployment tool. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the shape of the channel on the object being deployed because Applicant has not disclosed that shaping the channel a particular way provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have

expected both channels to perform equally as well with either shape, considering a deployment tool engagement portion is shaped the same as the channel.

Claims 23 and 24: The final, deployed product of Bray'034 contains legs that are integral with the body. The limitation "...each of the leg members is integrally formed with the body..." is being treated as a product-by-product limitation. Product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bray'034 in view of Small'499, as applied to Claim 1, further in view of Jobe (US Patent 5,634,926).

Bray'034 in view of Small'499 do not teach the use of a bioabsorbable material to make the device.

Jobe'926 teaches the use of a bioabsorbable material to make a similar device out of bioabsorbable materials (column 8, lines 46-62) so that they are absorbed by the body after a period of time. It would have been obvious to one of ordinary skill in the art to modify the device taught by Bray'034 in view of Small'499, by constructing it out of a bioabsorbable material, as taught by Jobe'926, so that it also has this advantage.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bray'034 in view of Small'499, as applied to Claim 1, further in view of Michelson (US Patent 6,620,163).

Bray'034 in view of Small'499 do not teach the use of a cell growth material to make the device.

Michelson'163 teaches the use of a cell growth material on a similar device in order to promote bone growth (column 13, lines 64 to column 14, line 3). It would have been obvious to one of ordinary skill in the art to modify the device taught by Bray'034 in view of Small'499 with a cell growth material, as taught by Michelson'163, so that it also has the stated advantage.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776